REMARKS

Claims 15 and 51-53 are in the application.

I. Claim 15 Is Enabled Under 35 U.S.C. § 112, First Paragraph

At page 3 of the Office Action, the Office rejects claims 15 and 48-50 under 35 U.S.C. § 112, first paragraph as allegedly lacking enablement because NIPK promoter sequences, genomic structure, transcriptional machinery, and a means of inhibition thereof are allegedly not disclosed by the Applicants.

As an initial matter, the rejection is moot as to claims 48-50 because claims 48-50 were cancelled, without prejudice or disclaimer, in Applicants' Amendment Under 37 C.F.R. § 1.116 filed August 6, 2008. Correction of the record is requested.

The Office is respectfully reminded that in order to sustain an enablement rejection, the Office has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention. *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). "It is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement. Otherwise, there would be no need for the applicant to go to the trouble and expense of supporting his presumptively accurate disclosure." 439 F.2d at 224, 169 USPQ at 370.

The standard for determining enablement of an invention in the U.S. is whether undue or unreasonable experimentation would be needed to practice an invention as claimed (*In re Wands*, 858 F.2d 731, 737, 8 USPQ 2d 1400, 1404 (Fed. Cir. 1988)). The Court of Appeals for the Federal Circuit set forth a number of factors that may be used in a determination as to whether undue experimentation would be required to practice an invention as claimed. In *In re Wands*, 858 F.2d 731, (Fed. Cir. 1988), the Court reversed the Examiner's rejection for lack of enablement holding that undue experimentation would not be required to practice the invention because it is know that in producing antibodies it is routine to first make monoclonal hybridomas to determine which hybridomas secrete antibodies with the desired characteristics. *In re Wands*, 8 U.S.P.Q.2d 1400 (CAFC 1988) states that the factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in *Ex parte Forman*, 230 U.S.P.Q. at 547.[1] The Court found that the Wands' specification provided the components needed to practice the invention.

Applicants respectfully disagree with the Office. Applicants teach the importance of NIPK, a kinase, and drug candidate compounds thereof in neural biophysiological processes. Applicants' specification and the state of the art is replete with examples of means by which to obtain drug candidate compounds to NIPK. For example, based on Applicants' disclosure, one having ordinary skill in the art conducting routine experimentation could practice the method

[1] In particular, it is noted that these factors include (1) the quantity of experimentation, (2) the amount to direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

recited by claim 15. In making the rejection the Office failed to consider that ever since findings (over 50 years ago) that reversible phosphorylation regulates the activity of glycogen phosphorylase, there has been exploration of protein phosphorylation in regulating protein function. The Office also failed to consider that DNA cloning and sequencing (which began in the mid-1970s) is applicable to Applicant's method and is useful in routinely experimenting on kinases. Indeed, a large family of eukaryotic protein kinases is known to exist from these efforts.

More specifically, examples of types of routine experimentation implicated in Applicant's claimed method include, *inter alia*, T. Hunter, *Cell* 50, 823 (1987); E. S. Lander et al., *Nature* 409, 860 (2001); G. M. Rubin et al., *Science* 287, 2204 (2000) ; G. Manning, G. Plowman, T. Hunter, S. Sudarsanam, *Trends Biochem. Sci.* 27, 514 (2002) ; J. C. Venter et al., *Science* 291, 1304 (2001) ; T. Hunter, G. D. Plowman, *Trends Biochem Sci.* 22, 18 (1997); P. Blume-Jensen, T. Hunter, *Nature* 411, 355 (2001) ; T. Hunter, *Cell* 100, 113 (2000) ; P. Cohen, *Nature Rev. Drug Discovery* 1, 309 (2002) ; *Science Online* at www.kinase.com/human/kinome; H. Yamaguchi, M. Matsushita, A. C. Nairn, J. Kuriyan, Mol. *Cell* 7, 1047 (2001). Because these teachings were not taken into account in making the lack of enablement rejection, the Office could not have properly weighed and applied the *Wands* factors therefore, the rejection cannot be maintained.

Regarding drug candidate compounds to NIPK, the Office failed to consider the routine experimentation implicated in Applicant's claimed method, including, *inter alia*, P. Cohen, *Nature Rev. Drug Discov.* 1, 309 (2002); D. Fabbro et al., *Pharmacol. Ther.* 93, 79 (2002); A. J. Barker et al., *Bioorg. Med. Chem. Lett.* 11, 1911 (2001); M. Hidalgo et al., *J. Clin. Oncol.* 19,

3267 (2001); C. L. Sawyers, *N. Engl. J. Med.* 340, 1330 (1999); B. J. Druker et al., *Nature Med.* 2, 561 (1996); B. J. Druker, N. B. Lydon, *J. Clin. Invest.* 105, 3 (2000); M. C. Heinrich et al., *Blood* 96, 925 (2000); C. D. Blanke, B. L. Eisenberg, M. C. Heinrich, *Curr. Treat. Options Oncol.* 2, 485 (2001); A. T. Van Oosterom et al., *Lancet* 358, 1421 (2001); P. T. Lakkakorpi, G. Wesolowski, Z. Zimolo, G. A. Rodan, S. B. Rodan, *Exp. Cell Res.* 237, 296 (1997); G. Kaur et al., *J. Natl. Cancer Inst.* 84, 1736 (1992); S. Zhai, A. M. Senderowicz, E. A. Sausville, W. D. Figg, *Ann. Pharmacother.* 36, 905 (2002); A. Kaiser et al., *Arch. Biochem. Biophys.* 386, 179 (2001); N. G. Oikonomakos et al., *J. Biol. Chem.* 275, 34566 (2000). Because the state of the art was not taken into account, the Office could not have properly weighed and applied the *Wands* factors. Based on the state of the art in view of Applicants' specification, the Office failed to establish a reasonable basis to question the enablement provided thus, the rejection should be withdrawn.

The Examiner's comments (i.e., at page 4 of the Office Action) allege that numerous examples are required in order to satisfy the enablement requirement of 35 U.S.C. § 112, first paragraph, which is incorrect. In fact, according to MPEP § 2164.02, the specification need not contain a single example.

Regarding the Examiner's assertion that some cells are not capable of nerve fiber formation, assuming *arguendo* that a single claimed embodiment is inoperable (i.e., a fibroblast), the inoperability of a single embodiment does not warrant a finding that the specification fails to enable the claims under 35 U.S.C. § 112, first paragraph. In fact, the Court of Appeals for the Federal Circuit addressed this very issue of enablement when it stated that "[e]ven if some of the

claimed combinations were inoperative, the claims are not necessarily invalid. 'It is not a function of the claims to specifically exclude...possible inoperative substances..." *Atlas Power Co. v. E.I. du Pont de Nemours & Co.*, 750 F.2d 169, 1576 (Fed. Cir. 1984).

Withdrawal of the lack of enablement rejection is kindly requested.

II. Claim 15 is Patentable Under 35 U.S.C. § 103(a)

At page 5 of the Office Action, the Office rejects claim 15 under 35 U.S.C. § 103(a) as allegedly being obvious over Meyers at al. (U.S. Patent Application Publication No. 2002/0034780) in view of Holocomb et al. (Dev. Biol. 172:307-323; 1995). The Office admits that Meyers et al. fail to describe assaying neurofibrillary degeneration.

To maintain a rejection under 35 U.S.C. §103, the cited references must teach or suggest each and every element of the claim. It is necessary to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007). Rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some *articulated reasoning* with some *rational underpinning* to support the legal conclusion of obviousness. The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield *predictable* results.

Applicants disagree with the Office. The Examiner failed to establish a *prima facie* case of obviousness because the Office failed to set forth any credible evidence or point out any suggestion in the cited references of Applicants' recited method. Nowhere is it indicated that it

was conventional in the art to arrive at the proposed combination (i.e., the Examiner failed to provide a sufficient reason or explicit analysis of why the disclosures of the references should be combined). There is no suggestion to combine the teachings and suggestions of Meyers et al. and Holocomb et al., a speculation advanced by the Examiner, except from using Applicants' invention as a template through a hindsight reconstruction of claim 15, which is forbidden. The law is clear that rejections on obviousness grounds cannot be sustained by mere conclusory statements and cannot be sustained using knowledge which was beyond the level of ordinary skill in the art at the time the claimed invention was made by including knowledge gleaned only from Applicants' disclosure, as in the present rejection.

Withdrawal of the rejection is therefore respectfully requested.

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The U.S. Patent and Trademark Office is hereby directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

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